K043570

## SECTION 2

# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of the 510(k) premarket notification for the ConforMIS, Inc. Unicondylar Knee Repair System is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

MAR 1 4 2005

## Summary of Safety and Effectiveness

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|---|---|
| **Submitted By:** | ConforMIS, Inc.<br>323 C Vintage Park Drive<br>Foster City, CA 94404<br>Phone 650-286-4151 |
| **Contact Person:** | Lyndall Erb, PhD<br>Director, Regulatory/Clinical & Quality Assurance |
| Phone | 650-286-4166 |
| FAX | 650-286-4160 |
| **Date:** | December 22, 2004 |
| **Trade/Proprietary Name** | Unicondylar Knee Repair System/<br>ConforMIS™ UCD |
| **Common Name** | Unicondylar Knee System |
| **Reference/Classification Name** | 21 CFR 888.3520 – Knee joint femorotibial metal/polymer non-constrained cemented prosthesis |

**Predicate Devices**

| Technological Characteristics | Indications for Use |
|---|---|
| • ConforMIS™ IPD Knee Interpositional (K033242) | • Zimmer Unicompartmental Knee System (K033363)<br>• EIUS Unicompartmental Knee System (K033769) |

**Intended Use:**

The ConforMIS™ Unicondylar Knee System is intended for use in Patients with:

- joint impairment due to osteoarthritis or traumatic arthritis of the knee
- Previous tibial condyle or plateau fracture, creating loss of function
- valgus or varus deformity of the knee

The ConforMIS™ Unicondylar Knee System is for use with cement.

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|---|---|
| **Device Description** | The ConforMIS Unicondylar Knee System is a device developed from patient CT scans to replace one compartment of the knee condyles. It is unconstrained in the anteroposterior and mediolateral directions and allows internal/external rotation between the femoral and tibial components. Movement is limited by the ligaments and other soft tissues surrounding the device. The device is designed to conform to the patient's anatomy as closely as possible based on the CT scans. |
| **Comparison to Predicate Devices:** | The ConforMIS Unicondylar Knee System is substantially equivalent to the ConforMIS IPD in technological characteristics in terms of design and production process, as well as materials and indications. It is substantially equivalent to the Zimmer Unicompartmental Knee System and the Repicci II Unicondylar Knee in that all have similar indications, design, materials and mechanical safety. All are intended for cemented use only. |
| **Performance Data** | Non-clinical Performance and Conclusions:<br>Testing completed as part of the design verification procedure for the ConforMIS Unicondylar Knee System found this device to be as safe and effective as the predicate devices, further confirming substantial equivalence.<br>Clinical Performance:<br>Clinical data and conclusions are not necessary to demonstrate substantial equivalence. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2005

Lyndall Erb, Ph.D.
Director, Regulatory/Clinical Affairs & Quality Assurance
ConforMIS, Inc.
323 C Vintage Park Drive
Foster City, California 94404

Re: K043570
Trade/Device Name: ConforMIS™ Unicondylar Knee Repair System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Code: HSX
Dated: February 18, 2005
Received: February 22, 2005

Dear Dr. Erb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

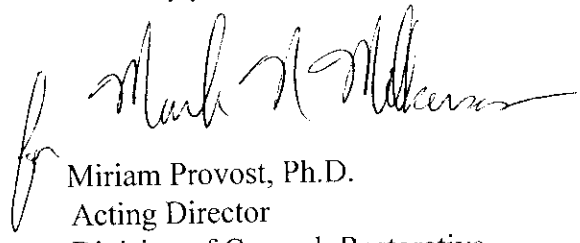
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-__. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K043570

Device Name: ConforMIS™ Unicondylar Knee Repair System

Indications for Use:

The ConforMIS™ unicondylar implant is intended for use in patients with:

- joint impairment due to osteoarthritis or traumatic arthritis of the knee
- previous tibial condyle or plateau fracture, creating loss of function
- valgus or varus deformity of the knee

The ConforMIS™ unicondylar implant is for use with bone cement.

for Mark N Milhous

**(Division Sign-Off)**
**Division of General, Restorative and Neurological Devices**

**510(k) Number** K043570

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)